

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO WAVE 4 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF DR. JIMMY W. MAYS**

Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, “Ethicon”), submit this memorandum in support of their motion to exclude the opinions and testimony of Dr. Jimmy W. Mays, Ph.D. This motion applies to the cases listed in Ex. A.

INTRODUCTION

Plaintiffs have designated Dr. Mays to offer general causation opinions regarding the alleged oxidative degradation of the Prolene polypropylene in pelvic mesh products manufactured by Ethicon, including TVT, TVT-O, TVT-Secur, TVT Abbrevio, TVT Exact, Gynemesh PS, Prolift, Prolift +M, and Prosima (collectively, “Ethicon Mesh Products”). Ex. B, Expert Report of Jimmy W. Mays (“Mays Report”). His testimony should be excluded because it does not meet the requirements of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591-95 (1993).

As the Fourth Circuit recently explained, *Daubert* presented a set of “guideposts to help a district court determine if expert testimony is sufficiently reliable[.]” *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017). Specifically, the *Daubert* Court concluded that a district court

should consider whether an expert's theory (i) has been tested; (ii) is subject to peer review; (iii) is subject to a known rate of error; and (iv) is generally accepted in the relevant scientific community. *Id.*; see also *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999). Significantly, the Fourth Circuit stated that although the *Daubert* analysis is a "flexible test" in which no single factor is dispositive, "[o]ne especially important factor for guiding a court in its reliability determination is whether a given theory has been tested." *Nease*, 848 F.3d at 231; see also *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 680-81 (S.D. W. Va. 2014) (testing failed to meet peer-reviewed standards).

Application of the *Daubert* criteria to Dr. Mays's opinions demonstrates that the Court should preclude him from testifying in the Wave 4 cases listed in Ex. A. Dr. Mays's opinions are unsupported by relevant scientific literature, testing, and the scientific community. For this reason, his degradation opinions are nothing but speculation, and should be excluded.

Ethicon is aware that the Court has permitted Dr. Mays to testify based on his literature review. See Mem. Op. and Order (*Daubert* Motion re: Jimmy W. Mays, Ph.D.), No. 2:12-md-02327, at 6 (S.D. W. Va. Aug. 25, 2016) [ECF # 2646] ("Wave 1 Mays Order"). Yet, Ethicon respectfully submits that the opinions he seeks to offer in this litigation warrant exclusion because they are unsupported by testing or scientific literature actually addressing the substance at issue in this litigation—the Prolene used in Ethicon Mesh Products.

This Court has disputed the validity of Ethicon's position that Prolene's chemical composition renders it materially distinct from other forms of polypropylene as "wholly conceived by lawyers, [and] unfounded in science." See *id.* (quoting *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014)). But Plaintiffs' own experts in this litigation

acknowledge that Prolene is unique due to its additive package, including antioxidants that retard *in vivo* oxidation.

In *Huskey v. Ethicon*, Plaintiffs' materials science expert—Dr. Scott Guelcher—conceded that Prolene is different from other forms of polypropylene because it contains proprietary additives. Specifically, Dr. Guelcher testified as follows:

Q. And what makes Prolene Prolene as opposed to simple polypropylene are the additives that you talked about, correct?

A. Yes. The brand name Prolene is defined by the additives that are added to the polypropylene.

....

Q. And those additives are what makes Prolene different from the other polypropylene medical devices on the market, correct?

A. There are many different grades of polypropylene; Marlex, Prolene, different grades –

The Court: Is that a yes or a no?

The Witness: I'm sorry. Yes.

Ex. C, *Huskey* 8/25/2014 Trial Tr. at 156:14–18; 157:11–17; *see also* Ex. D, Guelcher 3/23/16 Dep. 87:23–88:9 (“Q. Prolene has as different chemical composition than pure polypropylene, correct? A. Well, the—yeah, the composition's different because it has these additives.”).

But Dr. Guelcher is not the only expert for Plaintiffs to make this concession. Indeed, Dr. Mays testified that Prolene's additive package distinguishes it from other forms of commercial polypropylene, as well as pure polypropylene. Specifically, he testified as follows:

Q. Is it your testimony that polypropylene and Prolene are chemically different or chemically the same?

A. Prolene is a particular formulation of polypropylene.

Q. So they're chemically different; correct?

A. There are additives added.

Q. But they are chemically different? Polypropylene is chemically different than Prolene; correct?

A. Well, Marlex versus Prolene, the base polymer in both is isotactic polypropylene. There may be different additives in there. There may be different molecular weights of polypropylene use[d]. There may be different molecular weight distributions of the polypropylene that's used. So Prolene is a particular formulation of polypropylene.

Ex. E, Mays 3/2/16 Dep. 30:9-24.

Similarly, Dr. Duane Priddy's testimony demonstrates that Prolene's additives distinguish it from polypropylene:

Q. Doctor, as a materials scientist, would you agree that Prolene has a different chemical composition compared to pure polypropylene?

....

A. It's got stabilizers and additives, yes.

....

Q. Prolene and polypropylene are not identical, are they?

A. Prolene is polypropylene with additives.

Ex. F, Priddy 3/8/16 Dep. 103:21-104:5.

Given that Plaintiffs' experts have testified that Prolene's chemical formulation renders it different from other forms of polypropylene—including other commercially available forms—it simply cannot be said that Ethicon's position is merely the invention of Ethicon's lawyers.

Despite recognizing the singularity of Prolene, Dr. Mays did not conduct testing to support his opinions in this litigation.¹ And while he seeks to base his opinions on his review of scientific literature, none of the materials to which he cites support the proposition that the

¹ This Court has repeatedly excluded Dr. Mays's opinions based on tests he conducted on polypropylene manufactured by Boston Scientific. *See, e.g., Frankum v. Bos. Sci. Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at **14-15 (S.D. W. Va. May 1, 2015); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 685-91 (S.D. W. Va. 2014); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at **24-29 (S.D. W. Va. Sept. 29, 2014), *recon. denied*, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014).

Prolene used in Ethicon Mesh Products degrades in the human body. Accordingly, the Court should exclude Dr. Mays's opinions in their entirety. *See, e.g., Abarca v. Franklin Cty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) (“[A] reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted.”) (citation omitted), *mot. to certify appeal denied sub. nom., Abarca v. Merck & Co., Inc.*, No. 1:07-cv-388 DOC (DLBx), 2012 WL 137749 (C.D. Cal. Jan. 17, 2012).

In addition, the Court should preclude Dr. Mays from opining about the clinical complications allegedly caused by degradation. Dr. Mays lacks the qualifications necessary to offer such opinions, and fails to ground his opinions in reliable medical literature.

Finally, the Court should preclude Dr. Mays from testifying about Ethicon's knowledge, state of mind, and corporate conduct, as well as offering opinions that are nothing more than legal conclusions. This Court has repeatedly ruled that such testimony invades the province of the trier-of-fact, and Dr. Mays's opinions should be excluded on that basis.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at **1-3, (S.D. W. Va. July 8, 2014).

II. Dr. Mays's Degradation Opinions Are Unreliable.

Dr. Mays's central opinion in this litigation is that the Prolene used in Ethicon Mesh Products is subject to oxidation and degradation. But, even though he recognized that Prolene is different than other forms of polypropylene, Ex. E, Mays 3/2/16 Dep. 30:15-31:13, Dr. Mays

failed to test Prolene or base his opinions on reliable scientific literature specifically addressing Prolene.

A. Dr. Mays Admits That Prolene is Different Than Other Forms of Polypropylene.

At deposition, Dr. Mays conceded that Prolene is a unique form of polypropylene. *Id.* at 30:15-31:13. Specifically, he testified that while polypropylene is the base component in all forms of polypropylene, there are “different additives . . . different molecular weights of polypropylene . . . [and] different molecular weight distributions of the polypropylene that’s used,” which render Prolene a “particular formulation of polypropylene.” *Id.* at 30:18-24. Dr. Mays’s testimony is consistent with the evidence in this litigation—including the testimony of Plaintiffs’ other materials science experts. *See* Ex. C, *Huskey* 8/25/14 Trial Tr. 156:14–18; 157:11–17; Ex. D, *Guelcher* 3/23/16 Dep. 87:23-88:9; Ex. F, *Priddy* 3/8/16 Dep. 103:11-104:13.

It is inconsistent with the “intellectual rigor” employed by polymer chemists to make conclusions about the characteristics and behavior of a specific substance—here, Prolene—in the absence of testing or scientific literature actually addressing that substance. *Marsh v. W.R. Grace & Co.*, 80 F. App’x 883, 886 (4th Cir. 2003) (“The overall goal of the *Daubert* analysis is to ensure that ‘an expert, whether basing his testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’”) (quoting *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

B. Dr. Mays Did Not Test Prolene To Support His Degradation Opinions.

1. Testing is a key factor in determining the reliability of expert opinion.

In the recent case of *Nease v. Ford Motor Co.*, the Fourth Circuit reaffirmed the importance of testing in assessing the reliability of an expert’s opinion. The plaintiff in *Nease*

crashed a truck he was driving because he was unable to stop, allegedly due to the “mechanical binding” of the truck’s speed-control cable. 848 F.3d at 221-23. In relevant part, the plaintiff’s expert opined that the speed control assembly in plaintiff’s truck was defective because the design permitted contaminants to bind the speed control cable, and that such binding actually occurred in the plaintiff’s truck, resulting in the accident. *Id.* at 231.

The court explained that while *Daubert* is a “flexible test” and no single factor is dispositive, “[o]ne especially important factor for guiding a court in its reliability determination is whether a given theory has been tested.” *Id.* at 231. As the court observed, in the absence of supportive testing, an expert’s theory may be plausible and ““may even be right[,] . . . [but] it is no more than a hypothesis, and thus is not knowledge, nor is it based upon sufficient facts or data or the the product of reliable principles and methods applied reliably to the facts of the case.”” *Id.* at 232 (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010)).

In concluding that the expert’s testimony was unreliable, the court placed heavy emphasis on the fact that he failed to test his theory. Indeed, the court observed that the expert “never tested [the truck model at issue] to determine whether it is actually possible for enough debris to accumulate” such that the binding could occur, and “conceded that he never ran any tests to confirm his theory.” *Id.* at 231-32. For this reason, the court concluded that the expert’s “failure to test his hypothesis renders his opinions on the cause of [the] accident unreliable.” *Id.* at 232. In so holding, the court observed that proper “scientific methodology involves generating hypotheses and testing them to see if they can be falsified,” while the plaintiff’s expert merely “presented a hypothesis only [and] failed to validate it with testing.” *Id.*²

² The court found that the remaining *Daubert* factors likewise supported exclusion of the expert’s opinion because (i) he failed to publish or otherwise subject his theory to peer review; (ii) his poor “methodology” rendered it impossible to determine a potential rate of error; and (iii) a company document identifying potential failure modes did not constitute “general acceptance” of the expert’s theory. *Id.* at 232-33.

2. Dr. Mays's failure to test his opinions regarding Prolene renders his testimony unreliable.

Applying *Nease* to Dr. Mays's opinions, it is clear that the Court should preclude him from testifying in this litigation for the same reasons. Although Dr. Mays seeks to opine that Prolene is subject to oxidative degradation, he conceded at deposition that he has never conducted any tests on Prolene. Ex. E, Mays 3/2/16 Dep. at 34:13-35:10. Specifically, Dr. Mays admitted that he never tested Prolene to determine if it degrades or undergoes a reduction in mechanical properties. *Id.* at 34:13-20. He likewise never tested the durability, tensile strength, toughness, or any other physical property of Prolene. *Id.* at 36:8-19. Nor has he ever run any type of oxidation test on Prolene. *Id.* at 44:8-10.

Moreover, despite his testimony that a review of Prolene mesh explants and histological slides would be important to his opinions in this litigation, *id.* at 41:15-20; 42:4-11, Dr. Mays made no effort to conduct any such analysis, *id.* at 41:21-42:11. Indeed, Dr. Mays has never inspected any Prolene mesh explant, *id.* at 22:2-4, much less a Prolene explant that had oxidized or degraded, *id.* at 35:11-17. Nor has he ever seen a Prolene explant that had become embrittled or undergone a reduction of any physical property. *Id.* at 35:18-36:7.

In other words, just like the expert in *Nease*, Dr. Mays “presented a hypothesis only—he failed to validate it with testing.” 848 F.3d at 232.

Dr. Mays's failure to test Prolene in this litigation stands in stark contrast not only to the teachings of *Nease*, but to Dr. Mays's own testimony regarding the importance of testing in assessing a polymer for degradation. Indeed, Dr. Mays testified at deposition that it is necessary to conduct testing—such as spectroscopy and molecular weight analysis—to determine whether a material has degraded. Ex. E, Mays 3/2/16 Dep. 47:16-49:7. The importance of such testing to Dr. Mays's degradation opinions is evidenced by his efforts in pelvic mesh litigation against

other manufacturers. *See, e.g., Frankum v. Boston Sci. Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at **14-15 (S.D. W. Va. May 1, 2015) (excluding Dr. Mays's thermogravimetric analysis as unreliable and irrelevant); *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 685-91 (excluding Dr. Mays's microscopic and chemical testing as unreliable because it (i) failed to control for error or bias, and (ii) did not establish or adhere to testing protocols); *see also* Ex. E, Mays 3/2/16 Dep. 55:3-21 (testing of Boston Scientific meshes).³

Dr. Mays's "failure to test his hypothesis" that Prolene is subject to oxidative degradation *in vivo*—coupled with his failure to base this opinion on reliable scientific literature addressing Prolene, as discussed below—"renders his opinions . . . unreliable." *Nease*, 848 F. 3d at 232.

C. The Scientific Literature On Which Dr. Mays Relies Does Not Support His Degradation Opinions.

Having failed to conduct any tests on Prolene, Dr. Mays seeks to base his degradation opinions on his review of scientific literature and certain internal Ethicon documents. Ex. E, Mays 3/2/16 Dep. 37:18-38:1; *see also* Ex. B, Mays Report at 14-26. But none of the materials to which he cites actually stands for the proposition that the Prolene in Ethicon mesh products oxidizes and degrades *in vivo*. Dr. Mays's degradation opinions should be excluded on this basis. *See, e.g., Abarca*, 761 F. Supp. 2d at 1066 n.60 ("[A] reliable expert would not . . . misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted.").

1. Dr. Mays relies on studies that either do not assess Prolene implanted in the female pelvic floor, or are methodologically unsound.

Many of the studies on which Dr. Mays relies do not support his degradation opinions because they do not address Prolene. *See* Ex. B, Mays Report at 14-24 (discussing papers by

³ Furthermore, Dr. Mays agreed that it would be important to his opinions in this litigation to analyze explants and histological slides. *Id.* at 41:15-20; 42:4-11.

Liebert, Postlewait, Bracco, Clave, Lefranc, Imel, and Ostergard⁴). Again, it cannot be said that offering an opinion based on studies that do not address the subject matter of the opinion—Prolene—is consistent with the “intellectual rigor” employed by polymer chemists. *See Marsh*, 80 F. App'x at 886.

Even where Dr. Mays points to literature that addresses Prolene, the studies do not support his degradation opinions. At deposition, Dr. Mays testified that the only peer-reviewed literature analyzing Prolene on which he relies in this litigation are studies by Jongebloed, Costello, and Mary. Ex. E, Mays 3/2/16 Dep. 47:12-15.⁵ But scrutiny of these studies reveals that they simply do not stand for the proposition that Prolene implanted in the female pelvic floor is subject to degradation.

Exposure to Conditions Not Found in the Pelvic Floor. Dr. Mays seeks to rely on two studies by Jongebloed as evidence that Prolene exhibits surface degradation after implantation. *See* Ex. B, Mays Report at 15; *see also* Ex. H, W. Jongebloed & J. Worst, *Degradation of Polypropylene in the Human Eye: A SEM Study*, 64 Documenta Ophthalmologica 143 (1986); Ex. I, W. Jongebloed, *et al.*, *Mechanical and Biochemical Effects of Man-Made Fibres and Metals in*

⁴ Dr. Mays quotes liberally from a paper by Dr. Donald Ostergard—a urogynecologist who is a paid expert for plaintiffs in pelvic mesh litigation—that contains no testing, but purports to define when the FDA and mesh industry had knowledge of the alleged degradation of pelvic mesh. Ex. B, Mays Report at 23; *see also* Ex. G, D. Ostergard, *Degradation, Infection and Heat Effects on Polypropylene Mesh for Pelvic Implantation: What Was Known and When It Was Known*, 22 Int. Urogynecol. J. 771 (2011). But the fact that Dr. Ostergard's timeline was published does not permit Dr. Mays to circumvent the well-settled rule that an expert cannot testify about corporate knowledge or summarize documents for the jury. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009).

⁵ Although he declined to rely on it at deposition, Dr. Mays's Report identifies a paper by Dr. Vladimir Iakovlev that purportedly “observed a degradation layer or ‘bark’ and . . . proposed oxidative degradation as a mechanism consistent with their results.” Ex. B, Mays Report at 22. Notably, this paper is based on the unreliable methods employed by Dr. Iakovlev, whose degradation hypothesis has been disproven. *See* Mem. in Supp. of Mot. to Exclude Dr. Iakovlev, at 6-7 [ECF # 2070].

the Human Eye: A SEM Study, 61 Documenta Opthamologica 303 (1986). These studies are inapposite because they both addressed sutures that had been implanted in the human eye.

It is undisputed that all forms of polypropylene—including Prolene—are subject to oxidation when exposed to ultraviolet radiation. Thus, the fact that ocular sutures—which are necessarily exposed to UV radiation—oxidize after implantation in the eye is neither surprising nor germane to the Prolene used in Ethicon mesh products used in the female pelvic floor.

Not Prolene and Speculative. Dr. Mays seeks to base his degradation opinions on two studies by Costello. Ex. B, Mays Report at 16; *see also* Ex. J, C.R. Costello, *et al.*, *Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient*, 14 Surg. Innov. 168 (2007) (“Single Patient”); Ex. K, C.R. Costello, *et al.*, *Materials Characterization of Explanted Polypropylene Hernia Meshes*, 83B J. Biomed. Mater. Res Part B: Appl Biomater 44 (2007) (“Materials Characterization”). For instance, Dr. Mays seeks to inform the jury that the study found that “[c]racks and other surface degradations such as peeling of the fibers are indicative of the oxidation of polymeric materials.” Ex. B, Mays Report at 16 (quoting Single Patient, at 175). Dr. Mays also reports that Costello concluded that “[p]olypropylene is highly susceptible to the oxidative effects of the metabolites produced by phagocytic cells during the inflammatory response.” *Id.*

As an initial matter, the Materials Characterization study analyzed only mesh manufactured by C.R. Bard, and not the Prolene at issue in this litigation. For this reason, the findings of this study simply do not apply to Prolene. *See* Ex. E, Mays 3/2/16 Dep. 30:18-24.

Although the Single Patient study involved a polypropylene mesh manufactured by Ethicon, closer scrutiny of the study demonstrates that it does not support Dr. Mays’s opinion. The Single Patient study analyzed three different hernia mesh explants: (i) Gore-Tex; (ii) a

heavyweight polypropylene mesh manufactured by Bard; and (iii) Proceed, an Ethicon mesh composed of Prolene coated with oxidized cellulose. Ex J, Single Patient, at 169-70. Although the study found substantial evidence of oxidation and degradation of the Bard mesh, it reported no such evidence for the Proceed mesh. Ex. J, Single Patient at 172-75.⁶ In fact, in the same paragraph from which Dr. Mays quotes about the degradative propensity of polypropylene, Ex. B, Mays Report at 16, the Single Patient study reports that the Proceed “specimen did not possess any visible surface degradation,” Ex. J, Single Patient at 175. Thus, all of the findings reported by the Single Patient study about the degradation of polypropylene—that Dr. Mays seeks to attribute to Prolene in this litigation—are actually limited to the heavyweight mesh manufactured by Bard.

Unreliable methodology. Dr. Mays points to a study by Mary to support his opinion that Prolene undergoes oxidative degradation. Ex. B, Mays Report at 15-16; Ex. L, C. Mary, *et al.*, *Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery*, 44 Am. Soc’y Artificial Internal Organs J. 199 (1998) (“Mary Study”). But the Mary Study’s results were the product of an unreliable methodology.

Notably, the authors did not conduct any molecular weight analysis or test the mechanical properties of the sutures. Rather, they concluded that the Prolene sutures had oxidized based on FTIR test results showing a peak at 1,740^{cm}-, which “has been assigned to carbonyl stretching, and identifies the presence of surface oxidation, because the chemical structure of both pure polymers are devoid of this functional group.” Ex. L, Mary Study at 201. But as Dr. Mays

⁶ Indeed, the Single Patient study reported that scanning electron microscopy “revealed features identical to those of the pristine” Prolene Soft comparator, *id.* at 172; differential scanning calorimetry testing showed no statistically significant difference in melting temperature, *id.* at 173; thermogravimetric analysis testing showing “almost identical” values for the Proceed explant and pristine Prolene Soft sample, *id.* at 174; and histological examination revealed “minimal fibrotic tissue around the mesh” explant composed of Proceed, *id.* at 174.

admitted at deposition, the authors did not recognize in the study that 1,740^{cm⁻} is also the wavelength for one of the antioxidants used in Prolene. Ex. E, Mays 3/2/16 Dep. 123:7-124:10. Thus, the study failed to determine whether the peak at 1,740^{cm⁻} was merely a reading of the antioxidant package used in Prolene.

In addition, the sample preparation process used in the Mary study introduced error into the SEM results. Specifically, the study explains that after explantation, the sutures designated for SEM analysis were treated with either formalin or gluteraldehyde prior to cleaning. Ex. L, Mary Study at 200. The study ignores the fact that both formalin and gluteraldehyde crosslink with the proteinaceous layer on the fibers to form a hardened shell that can manifest as a cracked layer under SEM. *See* Ex. M, Expert Report of Shelby Thames, at 10, 16-21 (explaining that fixative agents used in sample preparation—formalin, formaldehyde, etc.—bond or crosslink with proteins adhered to the surface of an explant to form a hard, insoluble, and brittle shell around the surface of the explant).

2. Dr. Mays relies on unpublished Ethicon documents regarding Prolene sutures that do not support his opinion.

Dr. Mays also seeks to support his opinion that Prolene is subject to degradation by referring to certain unpublished Ethicon documents regarding Prolene sutures. Ex. B, Mays Report at 24-26. Yet, these internal documents do not support Dr. Mays's degradation opinions. In the event the Court permits Dr. Mays to testify based on his review of Ethicon's internal studies, the Court should allow Ethicon to introduce evidence regarding the FDA approval and regulation of Prolene polypropylene sutures.

a. Ethicon's unpublished studies do not support Dr. Mays's degradation opinions.

Dr. Mays bases his opinion that Prolene degrades such that it has diminished physical properties on a 1983 Prolene suture study. Ex. B, Mays Report at 24; Ex. E, Mays 3/2/16 Dep.

99:2-8; *see also* Ex. N, B. Matlaga Ltr. to Dr. A. Lunn (Mar. 23, 1983), ETH.MESH.15955438-73. But Dr. Mays admitted at deposition that the 1983 suture study only examined one fiber explant. Ex. E, Mays 3/2/16 Dep. 99:9-100:8. He also conceded that he could not rule out the possibility that the fiber analyzed in the study was damaged during excision. *Id.* at 100:23-101:4.

Dr. Mays also points to Ethicon's 1987 Prolene suture study as evidence that Prolene is subject to oxidative degradation. Ex. B, Mays Report at 25; *see also* Ex. O, IR Microscopy of Explanted Prolene (Sept. 30, 1987), ETH.MESH.12831391-1392. But the 1987 suture test does not support Dr. Mays's opinion that Prolene is subject to *in vivo* degradation, because it did not report a change in molecular weight in the sutures, which Plaintiffs' experts—including Dr. Mays—have acknowledged is a fundamental component of oxidative degradation. *See* Ex. E, Mays 3/2/16 Dep. 79:3-80:12 (“Q. But, Doctor, for oxidative degradation to occur, there must be loss of molecular weight, correct? A. Yes, when oxidative degradation occurs, there is degradation of molecular weight.”); *see also* Ex. P, Jordi 10/30/13 Dep. Tr. 173:25-174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene). Nor did the study make any findings that the sutures' mechanical properties—such as elongation and tensile strength—diminished.

Similarly, Dr. Mays relies on Ethicon's seven-year dog study of Prolene sutures as proof that Prolene oxidizes and degrades *in vivo*. Ex. Q, Seven Year Data for Ten Year Prolene Study (Oct. 15, 1992), ETH.MESH.09888220. But his reliance on the seven-year dog study is misplaced, because he admitted that it reported insignificant changes of molecular weight and “no molecular weight degradation.” Ex. E, Mays 3/2/16 Dep. 151:4-14. Dr. Mays also acknowledged that the study indicates that the sutures were plasticized *in vivo*, which would actually improve the toughness of the suture. *Id.* at 154:2-13.

Ultimately, none of these internal Ethicon documents supports Dr. Mays's opinion that the Prolene used in Ethicon Mesh Products degrades in the human body. Accordingly, the Court should exclude his opinions as unreliable.

III. The Court Should Exclude Dr. Mays's Opinions Regarding Clinical Complications Allegedly Caused By Degradation.

Dr. Mays seeks to inform the jury that the Prolene in Ethicon Mesh Products is subject to oxidative degradation following implantation, and this degradation causes the mesh to stiffen, which "can lead to pain, inflammation, and tissue damage in patients implanted with the device." Ex. B, Mays Report at 27. Furthermore, Dr. Mays seeks to opine that degraded Prolene is "behind all [mesh] removals" and "at the heart of the problems that all of [the plaintiffs in this litigation] had." Ex. E, Mays 3/2/16 Dep. at 50:8-10.

But Dr. Mays is not a medical doctor. *Id.* at 53:7. He is not a clinician. *Id.* at 52:23-24. Rather, he is a polymer chemist whose qualifications lie not in diagnosis of clinical complications, but in the "characterization of polymers[.]" *Id.* at 53:5-7. Dr. Mays's lack of qualifications to offer opinions regarding the clinical complications allegedly caused by degradation is, by itself, a sufficient basis for the Court to exclude his testimony on these issues. *See, e.g., Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011) (excluding expert testimony that went "beyond the experts' qualifications"), *clarified on reconsideration*, No. 2:04-0690, 2011 WL 2730908 (S.D. W. Va. July 13, 2011).

Even if Dr. Mays was qualified to offer opinions regarding medical causation—and he is not—there is no suggestion in Dr. Mays's Report or deposition transcript that he has ever conducted the differential diagnoses necessary to determine whether a patient's mesh caused clinical symptoms like pain, dyspareunia, or any other complications. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (explaining that a "[d]ifferential diagnosis, or

differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.”). Nor has he reviewed any medical records or spoken to any physicians such that he could opine that patients actually suffer from the clinical complications about which he seeks to testify. *See, e.g.*, Ex. E, Mays 3/2/16 Dep. 39:20-23.

Finally, Dr. Mays cannot base his opinions regarding complications on scientific or medical literature. At deposition, Dr. Mays conceded that he could only identify two sources of support for his opinion that the degradation of Prolene causes clinical complications: (i) a textbook by Professor David Williams, and (ii) a study by Dr. Uwe Klinge. *Id.* at 59:5-17, 60:8-18. But, importantly, Dr. Mays admitted that the Williams text does not actually address Prolene. *Id.* at 59:18-20.

Similarly, a review of the Klinge study reveals that while it involved a mesh manufactured by Ethicon, it analyzed a multifilament hernia mesh that had been treated with polyglactin 910—not the Prolene monofilament used in the Ethicon Mesh Products at issue in this litigation. *See* Ex. R, U. Klinge, *et al.*, *Shrinking of Polypropylene Mesh In Vivo: An Experimental Study in Dogs*, 164 Eur. J. Surgery. 965, 965 (1998). In addition, the Klinge study actually reported that the Ethicon hernia mesh elicited an inflammatory response that “was considerably less” than the Marlex mesh to which it was compared. *Id.* at 967. The study also found “moderate” fibrosis, “no scar plate,” “few fibroblasts,” and “increased vascularization.” *Id.* In other words, the Klinge study simply does not support Dr. Mays' opinion that the degradation of Prolene in Ethicon Mesh Products used in the female pelvic floor causes clinical complications in the human body.

The Court should preclude Dr. Mays from testifying about complications allegedly caused by degradation because he is not qualified to offer such opinions and his opinions are not based in scientific or medical evidence.⁷

In its August 25, 2016 *Daubert* order, this Court agreed that Dr. Mays cannot offer opinions regarding complications allegedly caused by degradation. Wave 1 Mays Order, at 6 (“Dr. Mays is simply not qualified to offer opinions on medical complications that may be caused by polymer degradation,” because he “is not a medical doctor . . . has not examined patients, and he has not conducted differential diagnoses.”). The Court’s ruling on this Motion should be no different.

IV. The Court Should Preclude Dr. Mays From Offering Opinions Regarding Ethicon’s Knowledge, State of Mind, or Corporate Conduct, as Well as His Legal Conclusions Masquerading as Expert Opinions.

Throughout his Report, Dr. Mays offers opinions that exceed the scope of proper expert testimony. For instance, Dr. Mays offers various opinions regarding Ethicon’s alleged knowledge, state of mind, or corporate conduct. By way of example, Dr. Mays asserts that “Ethicon was aware of the oxidation of Prolene prior to the introduction of the transvaginal mesh devices . . . but the company did not consider the risks associated with polypropylene oxidation[.]” Ex. B, Mays Report at 5; *see also id.* (“Ethicon did not take into account polypropylene’s propensity for oxidation during [the] design of its various Prolene based mesh products.”); 24 (“Ethicon was sufficiently aware of Prolene surface cracking and concerned enough about the consequences to form a committee to investigate the mechanism of cracking.”). But, as this Court has repeatedly held, a corporate defendant’s “knowledge, state of mind,

⁷ Notably, Dr. Mays did not inform physicians at the University of Tennessee—where he is employed—about his views regarding the alleged risks associated with using any polypropylene-based pelvic mesh until after he was cross-examined about his prior failure to do so. Ex. E, Mays 3/2/16 Dep. 57:16-58:2. He admitted that he has never shared his views about Prolene with his colleagues. *Id.* at 58:16-19.

alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.” *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013).⁸

Dr. Mays also seeks to offer legal conclusions in the guise of expert opinions. For example, Dr. Mays claims that “Prolene mesh is unreasonably dangerous, defective and is not suitable to serve as the permanent implants that they have been represented by Ethicon to be.” Ex. B, Mays Report at 6; *see also id.* at 22 (“[The] change in materials properties of a material implanted in the female pelvis poses unreasonable risk of harm and is defective from a design perspective in terms of the material choice made by Ethicon.”); *id.* at 27 (asserting that Ethicon mesh products are “unreasonably dangerous to sell for the uses Ethicon sold [them] for,” and that Ethicon “was unreasonable . . . to sell these devices for the intended applications.”). As this Court has recognized, “In the Fourth Circuit, ‘opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.’” *In re Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *21 (S.D. W. Va. Jan. 15, 2014) (quoting *U.S. v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)).

Dr. Mays also seeks to support his degradation opinions by spending several pages of his Report presenting his interpretation of a series of Ethicon’s internal documents. *See id.* at 24-26. But expert witnesses are not “permitted to merely read, selectively quote from, or ‘regurgitate’ the evidence” because a jury is more than capable of reading and summarizing documents on its own. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009); *see also In*

⁸ Dr. Mays also lacks the qualifications to offer opinions regarding Ethicon’s corporate knowledge or conduct. Dr. Mays is a polymer chemist. His resume does “not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion.” *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at 9 (E.D. Pa. June 20, 2000).

re Prempro Prods. Liab. Litig., 554 F. Supp. 2d 871, 880 (E.D. Ark. 2008) (striking improper expert's testimony that "simply . . . regurgitate[ed] . . . an exhibit, absent any expert analysis or opinion"), *aff'd in pertinent part*, 586 F.3d 547, 571 (8th Cir. 2009), *cert. denied sub. nom.*, *Wyeth LLC v. Scroggin*, 561 U.S. 1019 (2010). Accordingly, the Court should preclude Dr. Mays from testifying as to the content of Ethicon's internal documents.

For all of the reasons set forth above, the Court should preclude Dr. Mays from offering a narrative summary of Ethicon's documents or opinions concerning Ethicon's purported knowledge, state of mind, and corporate conduct. The Court should also bar Dr. Mays from presenting legal conclusions to the jury.

CONCLUSION

For the foregoing reasons, Ethicon requests that the Court exclude the opinion testimony of Dr. Mays, and grant such other and further relief as the Court deems proper under the circumstances.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO WAVE 4 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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